

14



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC

AUG 8 2001

Ray B. English  
President  
Foam Packaging, Inc.  
Post Office Box 1075  
Highway 61 South  
Vicksburg, Mississippi 39181

Dear Mr. English:

This responds to your request for flexibility in placement of the safe handling statement required on the labels of shell eggs. We hope that the following is helpful.

As you are aware, the recently promulgated regulation, 21 CFR 101.17(h), requires that the safe handling statement appear on the principal display panel (PDP) or the information panel (65 FR 76092, December 5, 2000). As defined in 21 CFR 101.1 the PDP is the "part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale." The information panel is defined in 21 CFR 101.2 as "that part of the label that is immediately contiguous and to the right of the [PDP] ..." or "if the top of the container is the [PDP] and the package has no alternate [PDP], the information panel is any panel adjacent to the [PDP]." Based on these definitions, the inlid of egg cartons does not meet the definition of the PDP or information panel. Thus, placement of the safe handling statement on the inlid does not comply with the placement requirements in 21 CFR 101.17(h)(2).

In a letter to the Food and Drug Administration (FDA) dated January 25, 2001, you requested that FDA allow the option of placing the safe handling statement on the inside lid (inlid) of egg cartons. The bases for your request were (1) high costs to change the graphic design for each brand that you produce for each customer, (2) lack of equipment to print on the side panels (i.e., the information panel), and (3) high costs to purchase equipment to print on the sides of egg cartons. In response to this request, FDA issued a letter dated April 1, 2001, stating that we would permit the safe handling statement on the inlid only when there is insufficient space on the PDP or information panel for all mandatory information. We pointed out that non-mandatory information such as artwork should not be considered when determining sufficiency of label space in accordance with 21 CFR 101.15.

We are now reconsidering placement of the statement on the inlid. We plan to issue a proposed rule to amend the regulation in 21 CFR 101.17(h) to include the option of placing the safe handling statement on the inlid. Until this rulemaking is complete, we will consider such requests on a case-by-case basis upon request by individual companies and it is unlikely that enforcement of the placement of the safe handling instructions on the inlid will be a high priority as long as the statement on the inlid is prominent. When judging whether the safe

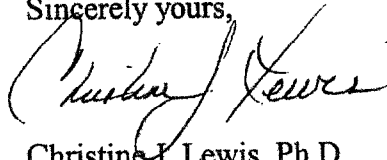
Page 2 – Mr. Ray B. English

handling statement is prominent, we may look to see if there is a referral statement on the PDP that instructs consumers to look at the label for the statement. (An example of such a statement is “see safe handling instructions inside.”) We may also consider whether any referral statement is in close proximity to the “Keep Refrigerated” statement that is still required by USDA regulations.

We would like to point out that the regulations in 21 CFR 101.17(h)(6) provide that States and localities may under their own jurisdictions enforce 21 CFR 101.17(h). Please understand that States and localities may choose to enforce the regulations as they now stand until they are amended through notice and comment rulemaking.

If you have further questions, please let us know.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Christine J. Lewis".

Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition